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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,046	08/08/2001	Syed Hossainy	ACS 54307 (22561)	2624

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FULWIDER PATTON LEE & UTECHT, LLP
Howard Hughes Center
Tenth Floor
6060 Center Drive
Los Angeles, CA 90045

EXAMINER	
PANTUCK, BRADFORD C	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,046	HOSSAINY ET AL.	
	Examiner	Art Unit	
	Bradford C Pantuck	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,57,58,60 and 62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14, 57, 58, 60, and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-7, 9-14, and 57, 58, and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,190,404 to Palmaz et al. Regarding Claims 1 and 11, Palmaz discloses an implantable medical device having a body portion and a roughened area on the inner surface of its body portion [see Fig. 8; Column 5, lines 1-8]. The inner surface can be considered to have either indentations or projections, depending on one's perspective. The plurality of grooves formed in the inner surface, as shown in Figures 9-15, cause the inner surface to be rough. That is, if one rubbed one's finger over the surface of the inside surface (301) of the stent, it would feel rough—i.e. *course* and not *smooth*. The word *asperity* is defined as "roughness or harshness, as of a surface." Thus, the inner surface of Palmaz's device has asperities—rough portions—due to the crevices in its surface, as described above.

2. Regarding Claims 2 and 11, Palmaz discloses indentations ("grooves") with pointed, rounded, and rectangular shapes [Column 5, lines 4-9; Figures 9, 10, and 11]. Palmaz discloses many different grooves [Fig. 8].

3. Regarding Claim 3, Palmaz discloses depositing material on the rough inside surface of the stent. In Column 6, lines 51-58, Palmaz describes putting a coating on the inner surface of the stent. The rough inner surface of the stent includes *both* the indentations ("grooves" 400) and the intervening inner surfaces (301) [see Fig. 8]. The *whole surface* shown in Figure 8 is rough and jagged.

4. Regarding Claim 4, the inner surface of Palmaz's device is rough because material has been selectively etched from the body portion [Column 5, lines 9-17].

5. Regarding Claims 5 and 12, the roughened area of the inner surface (301) of Palmaz's stent (300) includes substantially the entire inner surface of the body portion. As shown in Figure 8, and explained in Column 5, lines 19-52, the grooves (400, 400', 400", 400"') of Palmaz's stent can cover as much of the interior surface of the stent as is desired. In addition to the grooves, the rectangularly shaped holes *interspersed throughout the body* of the stent will also contribute to the rough feel of the stent [see Fig. 8].

6. Regarding Claims 6 and 13, the stent of Palmaz has a middle portion of its inner surface that is smooth [see Attachment #1]. Note that the *exemplary* middle section is chosen to illustrate that there is a middle portion that is smooth in the inner surface Palmaz's device. There are other smooth portions in the middle of the inner surface Palmaz's stent, as well. Specifically regarding Claim 13, the first and second ends of Palmaz's stent have *selected roughened regions* on the interior surface. Palmaz discloses that the designer of the stent may choose, *i.e. select*, how many/which kind of grooves to put on the interior surface of the stent [Column 6, lines 45-51].

7. Regarding Claims 7 and 60 the roughened portion Palmaz's tubular stent has a "roughness factor" greater than 40 nm. The Applicant, in the Specification discloses that 40 nm is the "upper limit of roughness factors typical of *polished stent surfaces*" [page 9, lines 28-29]. In other words, correctly polished stents for medical uses will have roughness factors less than 40 nm. Therefore, a stent with an *unpolished surface* or, *even more so*, a surface having *grooves* in it, must have a roughness factor, as defined by the Applicant [Equation 1, page 10], of greater than 40 nm. Palmaz's stent has an inner surface with asperities, as discussed above, and will have a roughness factor of much greater than 40 nm.

8. Regarding Claim 9, Palmaz discloses coating the inner surface of his stent with a non-thrombogenic material. His coating is a *layer* (218) of endothelial cells, which covers the inner surface of the stent [Fig. 7; Column 5, lines 56-62], separating the asperities on the inner surface of the stent from the flowing blood. Palmaz explains that he is intending to form a *layer of cells*, not just a few scattered cells coating the interior of the stent [Column 1, lines 54-58; Column 4, lines 32-36]. Endothelial cells are the cells that coat the inner surfaces of natural blood vessels and the heart. When these cells are removed, platelets form. Platelets are the kind of cells that are *thrombogenic*, i.e. cause clotting. Endothelial cells *prevent thrombosis*, i.e. non-thrombogenic, and allow the interior of the stent to remain open [Column 1, lines 35-65].

9. Regarding Claim 10, Palmaz's stent has a body portion (300). The roughened portion of the stent (300) includes the flat inner surface (301) of the stent with the

intervening grooves (400). The depth of each groove is .5-10 microns, which is a depth less than the thickness of the body portion (300), as shown in cross-sectional Figures 9-25. For example, Figure 10 shows very clearly that the depth of the groove (400) is less than the thickness of the wall between the inner and outer surface. Therefore, the roughened portion includes a region (i.e. at each groove) where the wall is thinner than the selected thickness.

10. Regarding Claims 14 and 62, Palmaz discloses coating the inner surface of the stent [Column 6, lines 52-58]. *Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Clearly, the coating is capable of increasing friction of the inner surface of the stent. Applicant claims no structure that sets the claimed stent apart from the prior art stent.*

11. Regarding Claim 57, Palmaz discloses coating the inner surface of a balloon-expandable stent before deployment in the patient's vasculature [Column 6, lines 52-58]. Palmaz's coating is only applied to the inner surface, and is applied over an asperity. In this context, an asperity is considered to be a small bump or projection. The spaces in between the grooves of the inner surface of Palmaz's stent are exactly that—projections. For example, the coating would be applied to surface 301 in Figure 12.

12. Regarding Claim 58, Palmaz discloses coating the inner surface of a balloon-expandable stent before deployment in the patient's vasculature [Column 6, lines 52-58]. There are many different asperities, in between the many different grooves. A

coating inherently reduces the interaction between the asperities (301) and the blood in the lumen, by separating one from the other.

13. Regarding Claim 64, the inner surface of Palmaz's device is rougher than the outer surface, because the inner surface has many grooves, whereas the outer surface has none. Although the rectangularly shaped holes interspersed throughout the body of the stent will increase the roughness of the outer surface, they will equally increase the roughness of the inner surface. The *inner surface has grooves in addition to the holes*, and will consequently be rougher.

14. Claim 62 is rejected under 35 U.S.C. 102(e) as being anticipated by Publication No. US 2003/0028241 A1 to Stinson. Stinson discloses a stent made out of nitinol {paragraph [0015]}, intended to be inserted into the body, and capable of being delivered with a balloon catheter. The stent surface is roughened to have a roughness factor of 16 to 125 microinches (407-3175 nm) in order to better hold a radiopaque coating {paragraph [0070]}. Stinson discloses that either the inner or outer surface of the stent can be roughened to perform such a function {paragraph [0019]}. The coating, *being in particulate form* {paragraph [0064]} (rather than in a polished, solid form), will certainly increase the coefficient of friction of the inner surface of the stent. Such a coating is applied directly to the roughened surface. The coating may be mixed with wax, a sticky and tacky material with a high coefficient of friction itself {paragraph [0071]}.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,190,404 to Palmaz et al. Palmaz does not specifically disclose the roughness factor of the inside surface of his stent being above 100 nm, but it can be inferred that his roughness factor [as defined by the Applicant] is greater than 100 nm, as explained below. As previously explained, the Applicant, in the Specification discloses that 40 nm is the "upper limit of roughness factors typical of *polished stent surfaces*" [page 9, lines 28-29]. In other words, correctly polished stents for medical uses will have roughness factors less than 40 nm. Therefore, a stent with an *unpolished surface* or, *even more so*, a surface having *grooves* in it, must have a roughness factor, as defined by the Applicant [Equation 1, page 10], of greater than 40 nm. Palmaz's stent has an inner surface with asperities, as discussed above, and will have a roughness factor of much greater than 40 nm. The grooves in Palmaz's stent .5-10X10(-6) meters deep and 2-40X10(-6) meters wide. Therefore, Palmaz's stent has significant grooves and because the difference between 40 nm and 100 nm is so minute, it is clear that the interior of Palmaz's stent will be *significantly* rougher than a polished metal surface with a roughness of 40 nm.

Further, Palmaz's grooves have substantially the same shape as the Applicant's grooves. For example Palmaz's Figure 12 is very similar to the Applicant's rendering of the shape of his grooves in Figure 6E. Palmaz *discloses the same grooves as the Applicant*, and discloses arranging the grooves in as great a frequency as is desired [Column 5, lines 36-43]. Although it is unclear what dimensions the grooves of the Applicant's inner surface have, Palmaz discloses having the same grooves on the interior of his stent as the Applicant, so consequently his roughness factor must be assumed to be the same as the Applicant's: over 100 nm.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Publication No. US 2002/0114823 A1 to Sirhan et al.

U.S. Patent No. 6,395,326 B1 to Castro et al.

U.S. Patent No. 6,558,733 B1 to Hossainy et al.

Response to Arguments

17. Applicant's arguments, see Appeal Brief, filed 07/13/2004, with respect to the rejection(s)of claim(s) 62 under U.S. Patent No. 6,190,404 B1 to Palmaz et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Publication No. US 2003/0028241 A1 to Stinson.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (703) 308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
BCP
October 19, 2004

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER